Institutional Certification for Multicenter Studies[1]

February 23, 2015

Carol Pontzer, PhD
GDS Program Administrator [INSTITUTE], NIH, DHHS [ADDRESS]
Bethesda, MD 20892-7395

Re: Institutional Certification of University of Maryland School of Medicine to Accompany Submission of the Dataset for Mid-Career Award in Patient-Oriented Research (K24) to an NIH-designated data repository.

Dear Dr. Pontzer,
The submission of data to the NIH-designated data repository is being made with institutional approval from University of Maryland School of Medicine, along with appropriate institutional approvals from collaborating sites, as listed here:

Massachusetts General Hospital

The University of Maryland School of Medicine hereby assures that submission of data from the study entitled Mid-Career Award in Patient-Oriented Research (K24) to an NIH-designated data repository meets the following expectations, as defined in the Genomic Data Sharing Policy:

• The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.[2]

• Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated in the table on page 3.[3]

The use of aggregate-level data for general research use is not inconsistent with informed consent.[4]

Yes No

The display of variant alleles and/or frequencies, from this study in public variation archives (i.e., dbSNP and dbVar)[5] is not inconsistent with informed consent.

Yes No

• The identities of research participants will not be disclosed to NIH-designated data repositories.

• An Institutional Review Board and/or Privacy Board, and/or equivalent body, as applicable, has

reviewed the investigator's proposal for data submission and assures that:

- o The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46.[6]
- o Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;[7]
- o Consideration was given to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing;
- o To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing; and
- o The investigator's plan for de-identifying datasets is consistent with the standards outlined in this Policy (see section IV.C.1.).

The data are to be made available through unrestricted[8] or controlled-access[9]

Sincerely,
Authorized Institutional Official:[10]

Name: Dennis J. Paffrath Title: Assistant Vice President, SPA
Signature: Dennis J Paffrath Date: 3/11/2015
Investigator:
Name: CLAIRE M. FRASER Title: DIRECTOR
Signature: Claire M. Fraser Date: 3/10/15

Authorized Institutional Official:[10]

Name: _____ Title: _____
Signature: _____ Date: _____
Investigator:
Name: _____ Title: _____
Signature: _____ Date: _____

[1] Certification must be provided for all sites contributing samples. The primary site may submit *one* Institutional Certification indicating that they are providing certification on behalf of all collaborating site. Alternatively, each site providing samples may provide their own Institutional Certification.
[2] For the submission of data derived from cell lines or clinical specimens lacking research consent that were created or collected before the effective date of this Policy, the Institutional Certification needs to address only this item.
[3] For guidance on drafting data use limitations, see NIH Points to Consider in Drafting Effective Data Use Limitation Statements, http://gwas.nih.gov/pdf/NIH_PTC_in_Drafting_DUL_Statements.pdf
[4] Aggregate-level data include summary statistics from the research study, such as allele frequencies or effect sizes and p-values for test of association. If "yes" is checked, your aggregate-level data will be included in the Compilation of Aggregate Genomic Data, a collection of

analyses across many dbGaP studies that can be accessed with a single Data Access Request.

[5] The Single Nucleotide Polymorphism Database (dbSNP) is a public archive for genetic variation (apparently neutral polymorphisms, polymorphisms corresponding to known phenotypes, and regions of no variation) within and across species. The Database of Genomic Structural Varian (dbVar) is a collection of genomic structural variation data, typically 50 nucleotides in length or longer, for different organisms. For more information, see: http://www.ncbi.nlm.nih.gov/SNP/ and http://www.ncbi.nlm.nih.gov/dbvar/.

[6] 45 CFR Part 46. Protection of Human Subjects. See http://www.gpo.gov/fdsys/pkg/CFR-2011-title45-vol1/xml/CFR-2011-title45-vol1-part46.xmL

[7] As noted earlier, for studies using data or specimens collected before the effective date of this Policy, the IRB, privacy board, or equivalent body should review informed consent materials to ensure that data submission is not inconsistent with the informed consent provided by the research participants.

[8] Data made publicly available to anyone

[9] Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project.

[10] A senior official at an institution who is credentialed through NIH eRA Commons system and is authorized to enter the institution into a legally binding contract and sign on behalf of an investigator who has submitted data or a data access request to NIH

For guidance on drafting data use limitations, please refer to the NIH Points to Consider in Drafting Effective Data Use Limitation Statements found at:
http://gds.nih.gov/pdf/nih_ptc_in_drafting_dul_statements.pdf.

Consent Group Title Options
(select one of the four categories below)
Data Use Limitations
General Research Use (select any that apply) IRB approval required
Use of the data is limited only by the terms of the Data Use Certification.
Requestor must provide documentation of local IRB approval.
Publication required
Requestor agrees to make results of studies using the data available to the larger scientific community.
Collaboration required
Requestor must provide a letter of collaboration with the primary study investigator(s).
Not-for-profit use only
Use of the data is limited to not-for-profit organizations.
Health/Medical/Biomedical (select any that apply) IRB approval required
Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Publication required
Requestor agrees to make results of studies using the data available to the larger scientific community.
Collaboration required
Requestor must provide a letter of collaboration with the primary study investigator(s).
Not-for-profit use only
Use of the data is limited to not-for-profit organizations.
Methods
Use of the data includes methods development research (e.g., development of software or algorithms)
Genetic studies only
Use of the data is limited to genetic studies only.
Disease-specific [list disease] (select any that apply) IRB approval required
Use of the data must be related to the specified disease.
Requestor must provide documentation of local IRB approval.
Publication required
Requestor agrees to make results of studies using the data available to the larger scientific community.
Collaboration required
Requestor must provide a letter of collaboration with the primary study investigator(s).
Not-for-profit use only
Use of the data is limited to not-for-profit organizations.
Methods
Use of the data includes methods development research (e.g., development of software or algorithms)
Related disorders
Use of the data is limited to genetic studies of the specified disease and related conditions, such as _____.
Genetic studies only
Use of the data is limited to genetic studies only.
Other
[ENTER CUSTOMIZED TEXT, IF APPLICABLE]

Using the table above, please indicate in the table below the consent group(s) for each collaborating study site

Collaborating Site Name
Study Name
Consent Group Title
Ex. University of Wisconsin
Cold Cohort Study
Health/Medical/Biomedical
University of Wisconsin
Cold Cohort Study
Disease-specific [Lung Cancer] Research
- *IRB approval*
- *Methods*

Addendum to the Data Use Certification Agreement
Modification of Data Security Terms and Best Practices

Effective for all dbGaP Data Access Requests submitted on or after March 23, 2015,
Section 6 of the Data Use Certification Agreement is replaced in its entirety by the following:

6. Data Security and Data Release Reporting

The Requester and Approved Users, including the institutional IT Director, acknowledge NIH's expectation that they have reviewed and agree to manage the requested dataset(s) according to the current NIH Security Best Practices for Controlled-Access Data Subject to the GDS Policy and the institutional IT security requirements and policies, and that the institution's IT security requirements and policies are sufficient to protect the confidentiality and integrity of the NIH controlled-access data entrusted to the Requester.

If approved by NIH to use cloud computing for the proposed research project, as outlined in the Research and Cloud Computing Use Statements of the Data Access Request, the Requester acknowledges that the IT Director has reviewed and understands the cloud computing guidelines in the NIH Security Best Practices for Controlled-Access Data Subject to the GDS Policy.

Requesters and PIs agree to notify the JARDE DAC of any unauthorized data sharing, breaches of data security, or inadvertent data releases that may compromise data confidentiality within 24 hours of when the incident is identified. As permitted by law, notifications should include any known information regarding the incident and a general description of the activities or process in place to define and remediate the situation fully. Within 3 business days of the JARDE DAC notification, the Requester, through the PI and the Institutional Signing Official, agree to submit to the JARDE Data Access Committee a detailed written report including the date and nature of the event, actions taken or to be taken to remediate the issue(s), and plans or processes developed to prevent further problems, including specific information on timelines anticipated for action.

All notifications and written reports of data security incidents should be sent to:
JARDE Data Access Committee URGENT: ujardedac@mail.nih.gov
GDS mailbox: gds@mail.nih.gov

NIH, or another entity designated by NIH may, as permitted by law, also investigate any data security incident. Approved Users and their associates agree to support such investigations and provide information, within the limits of applicable local, state, and federal laws and regulations. In addition, Requesters and Approved Users agree to work with the JARDE and NIH to assure that plans and procedures that are developed to address identified problems are mutually acceptable and consistent with applicable law.